

AMENDMENTS TO THE CLAIMS:

Claims 1-27 (cancelled).

28. (Currently Amended) A synthetic transport entity complex for transferring a nucleic acid of interest across a biological membrane into a cell ~~to a specific location within or on a cell,~~ wherein the complex ~~which~~ is comprised of two or more functional elements (FE), each of ~~are~~ is complexed to a binding element (BE) in the form of a peptide nucleic acid (PNA) ~~or a derivative or analogue thereof,~~ and a nucleic acid carrier, which comprises at least ~~one~~ two BE target ~~sequence~~ sequences and a nucleic acid of interest in a vector; said ~~complex~~ carrier being hybridized to said ~~carrier~~ complex using the BE-BE interaction.

29. (Currently Amended) The transport entity complex according to claim 28, wherein said two or more FEs provide different functions.

30. (Currently Amended) The transport entity complex according to claim 28, wherein said vector is a plasmid or an oligonucleotide.

31. (Currently Amended) The transport entity complex according to claim 28, wherein the carrier includes a detectable marker element.

32. (Currently Amended) The transport entity complex according to claim 28, wherein the nucleic acid of interest is a gene encoding a peptide, a protein or an RNA.

33. (Currently Amended) The transport entity complex according to claim 28, wherein said BE and FEs are separated by linker elements.

34. (Currently Amended) The transport entity complex according to claim 28, which comprises more than one FE-BE-complex, each one of which is hybridized to a separate BE target sequence present on the same carrier.

35. (Currently Amended) The transport entity complex according to claim 28, wherein the FE is a nuclear localization signal (NLS), or a fragment thereof exhibiting nuclear localizing signal properties.

36. (Currently Amended) The transport entity complex according to claim 28, wherein the FE is a protein exhibiting

properties enabling both membrane translocation and nuclear transport.

37. (Currently Amended) A method for transferring a nucleic acid of interest across a biological membrane of a target cell to ~~a specific location within or on a cell by the use of~~ comprising administering to the cell the synthetic transport entity complex according to claim 28, ~~comprising the steps of:~~

- ~~(a) providing a carrier molecule comprising the nucleic acid of interest in a vector and a binding element (BE) target sequence;~~
- ~~(b) providing a complex by coupling two or more functional elements (FE) to a binding element (BE);~~
- ~~(c) hybridizing the BE of said complex to the BE target of said carrier; and~~
- ~~(d) contacting said transport entity with said biological membrane to provide for a transfer of the nucleic acid of interest across said membrane.~~

38. (Currently Amended) The method according to claim 37, wherein in said transport complex said two or more FEs provide different functions.

39. (Currently Amended) The method according to claim 37, ~~wherein in step (b), a complex is provided,~~ wherein in said transport complex said BE and FEs are separated by linker element(s).

40. (Currently Amended) The method according to claim 37, wherein ~~in step (a),~~ in said transport complex the carrier provided is a plasmid or an oligonucleotide vector comprising said nucleic acid of interest and at least one target sequence.

41. (Currently Amended) The method according to claim 37, wherein ~~in step (a),~~ in said transport complex a detectable marker element is ~~also~~ inserted in said carrier.

42. (Currently Amended) The method according to claim 37, wherein in said transport complex the nucleic acid of interest is a gene encoding a peptide, a protein or an RNA.

43. (Currently Amended) The method according to claim 37, ~~which~~ wherein said complex comprises more than one FE-BE complex, each one of which is hybridized to a separate BE target sequence present on the same carrier.

44. (Previously Presented) The method according to claim 37, wherein the biological membrane is a cell wall.

45. (Currently Amended) The method according to claim 37, wherein the biological membrane is a nuclear membrane, and wherein at least one functional element (FE) of said two or more functional elements is a protein, which enables both membrane translocation and nuclear transport of the nucleic acid of interest.

46. (Currently Amended) The method according to claim 37, wherein in said transport complex the FE is a nuclear localization signal (NLS), or a fragment thereof exhibiting nuclear localizing signal properties.

47. (Currently Amended) The method according to claim 37, wherein in said transport complex the FE is a protein provided in said complex, which enables both membrane translocation and nuclear transport of the nucleic acid of interest.

48. (Currently Amended) A kit comprising components for making a transport entity capable of transferring a nucleic acid of interest across a biological membrane into ~~to a specific location within or on~~ a cell, which kit comprises ~~a binding~~

element at least two binding elements (BE) in the form of a peptide nucleic acid (PNA); two or more functional elements (FE); a plasmid containing said nucleic acid of interest; an oligonucleotide comprising a target for ~~said BE~~ each of said BEs and being suitable for cloning in a ~~desired~~ said plasmid ~~containing said nucleic acid of interest~~; and optionally reagents suitable for such transfer.

49. (Previously Presented) The kit according to claim 48, wherein said two or more FEs provide different functions.

50. (Previously Presented) The kit according to claim 48, wherein at least one functional element (FE) is a nuclear localization signal (NLS), or a fragment thereof exhibiting nuclear localizing signal properties.

51. (Previously Presented) The kit according to claim 48, wherein the FE is a protein provided in said complex, which enables both membrane translocation and nuclear transport of the nucleic acid of interest.

52. (Currently Amended) The transport entity complex according to claim 35, wherein said NLS is a SV40 large T antigen protein.

53. (Currently Amended) The transport ~~entity~~ complex according to claim 36, wherein the FE is an HIV protein.

54. (Currently Amended) The transport ~~entity~~ complex according to claim 53, wherein said HIV protein is TAT.

55. (Currently Amended) The method according to claim 46, wherein in said transport complex said NLS is a SV40 large T antigen protein.

56. (Currently Amended) ~~the~~ The method according to claim 47, wherein in said transport complex the FE is an HIV protein.

57. (Previously Presented) The method according to claim 56, wherein said HIV protein is TAT.

58. (Previously Presented) The kit according to claim 50, wherein said NLS is a SV40 large T antigen protein.

59. (Cancelled)

60. (Cancelled)

REMARKS

Claims 28-58 are pending. No new matter has been added by way of the present amendment. For instance, claims 28, 37, 45 and 48 have been amended as suggested by the Examiner, for instance these claims now adopt the language outlined at pages 4-6 of the outstanding Office Action. These amendments are also supported by the present specification, for instance, reference is made to at least page 3, lines 28-31 and page 11, line 19 to page 12, line 7. Amendments have also been made to the dependent claims as to parallel the amended language of claims 28, 37, 45 and 48. Lastly, claims 59-60 have been cancelled. Accordingly, no new matter has been added.

Applicants further submit that no new issues have been raised by way of the present submission. Applicants have simply adopted the suggested claim language set forth by the Examiner. These amendments will therefore remove issues and should therefore be entered.

In the event that the present submission does not place the application into condition for allowance, entry thereof is respectfully requested as placing the application into better condition for appeal.

In view of the following remarks, Applicants respectfully request that the Examiner withdraw all rejections and allow the currently pending claims.

Issues Under 35 U.S.C. §112, first paragraph

The Examiner has rejected claims 28-58 under 35 U.S.C. §112, first paragraph, written description, for the reasons recited at pages 2-5 of the outstanding Office Action. In particular, the Examiner asserts that Applicants were not in possession of the invention as claimed. Applicants traverse this rejection.

Applicants have amended claims 28, 37, 45 and 48 to reflect the Examiner's suggested claim language as set forth on pages 4-5 of the outstanding Office Action. Accordingly, as indicated by the Examiner, by adopting such claim language, this rejection is moot. Reconsideration and withdrawal thereof are respectfully requested.

The Examiner has also rejected claims 28-58 under 35 U.S.C. §112, first paragraph, enablement, for the reasons recited at pages 5-8 of the outstanding Office Action. Applicants traverse this rejection. Applicants have adopted the Examiner's suggested claim language (refer to page 5-6 of the outstanding Office Action). Accordingly, this rejection is moot.

Reconsideration and withdrawal thereof are respectfully requested.

Issues Under 35 U.S.C. §102(e)/103(a)

The Examiner has rejected claims 48-51 and 58 under 35 U.S.C. §102(e) as being anticipated by, or in the alternative, under 35 U.S.C. §103(a) as being obvious over Felgner, USP 6,165,720 (hereinafter referred to as Felgner '720). Applicants traverse this rejection.

The Examiner asserts that the cationic lipid and the nuclear localization signal (NLS) of Felgner '720 serve as the two functional elements (FE) required by the claims. Applicants disagree with the Examiner's characterization of Felgner '720. While cationic lipids might be viewed as a functional element in that they can mediate transfection, they do not specifically bind to the PNA (corresponding to the binding element of the present invention). Rather, the cationic lipids form a complex with the plasmid. Accordingly, the cationic lipids of Felgner '720 cannot be compared with the functions elements of the present invention.

Additionally, the present claim, as amended, are distinct from Felgner '720. Specifically, Felgner '720 fails to disclose the use of at least two binding elements (BE) as required by the rejected claims. Accordingly, no anticipation, nor obviousness,

exists based upon Felgner '720. Reconsideration and withdrawal of this rejection are respectfully requested.

Renewed Request for Initialed Form PTO-1449

On March 13, 2001, Applicants filed an Information Disclosure Statement including a Form PTO-1449 which listed five references. With the exception of one of these references (WO 93/19768), the references cited in this Form PTO-1449 were duplicated in the Information Disclosure Statement filed on June 13, 2001. The Examiner has returned an initialed copy of the June 13, 2001 Form PTO-1449. However, WO 93/19768 listed on the Form PTO-1449 filed on March 13, 2001, has not yet been initialed by the Examiner. The Examiner is therefore respectfully requested to provide Applicants with an initialed copy of this Form PTO-1449 indicating that this reference has been considered.


If the Examiner has any questions or comments, please contact Craig A. McRobbie, Registration No. 42,874 at the offices of Birch, Stewart, Kolasch & Birch, LLP.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any

additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17; particularly, extension of time fees.

Respectfully submitted,

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